

Attorney Docket No.: **DC-0190**
Inventors: **Hamilton and Stanton**
Serial No.: **10/089,475**
Filing Date: **August 12, 2002**
Page 4

REMARKS

Claims 1-11 are pending in the instant application. Claim 9 has been rejected. Claims 1-8 and 10-11 have been canceled. Claim 9 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Election/Restriction Requirement Under 35 U.S.C. §121

The restriction requirement placing the claims into Groups I-VII has been deemed proper and made final. Further, the Examiner has suggested that Group I and Group VI claims are separate and distinct inventions because the invention of Group I can be used in other methods than those of Group VI. Claims 1-8 and 10-11 are withdrawn from further consideration. Accordingly, Applicants are canceling claims 1-8 and 10-11 without prejudice, reserving the right to file continuing applications for the canceled subject matter.

II. Objection of Claims

Claim 9 has been objected to for being dependent on claim 4, which is drawn to a non-elected invention. Accordingly, Applicants have amended claim 9 to remove reference to 4. It is therefore respectfully requested that this objection be withdrawn.

Attorney Docket No.: DC-0190
Inventors: Hamilton and Stanton
Serial No.: 10/089,475
Filing Date: August 12, 2002
Page 5

III. Rejection of Claims Under 35 U.S.C. §112

Claim 9 has been rejected under 35 U.S.C. §112, first paragraph, for not enabling any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. The Examiner suggests that while the specification is enabling for a method for identifying agents which increase functional cell surface expression of deltaF508 CFTR protein by exposing cells comprising a genetic construct comprising human CFTR coding sequence and an eGFP reporter gene to the agent, measuring expression levels or trafficking of CFTR to the membrane, and comparing the levels of CFTR expression or trafficking to controls, does not reasonably provide enablement for a method for identifying agents for use in the treatment of cystic fibrosis.

Claim 9 has been further rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner suggests that, given the diverse nature of the CF phenotype, the scope of claim 9 includes numerous other methods, and the genus is highly variant because a significant number of differences between genus member is permitted.

Claim 9 has also been rejected under U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner suggest that claim 9 is

Attorney Docket No.: DC-0190
Inventors: Hamilton and Stanton
Serial No.: 10/089,475
Filing Date: August 12, 2002
Page 6

vague and indefinite in that it is drawn to methods of identifying agents which are useful in the treatment of CF, because it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Applicants respectfully traverse these rejections.

In an effort to facilitate the prosecution of this application and in accordance with the Examiner's suggestions, Applicants have amended claim 9 to recite that the method of the invention is for identifying agents which increase functional cell surface expression of a mutant CFTR protein. Support for this amendment can be found at page 7, lines 29-33. Applicants believe that the specification fully supports such a claim in demonstrating that agents such as doxorubicin increase CFTR protein levels, levels of CFTR protein found at the cell surface, and CFTR-associated chloride currents in cells expressing a GFP-tagged mutant human CFTR. As these cells can be assayed for functional activity of CFTR, as evidenced by CFTR-associated chloride current measurements disclosed in the instant application at pages 9 and 10, claim 9 has been further amended to include that activity levels of CFTR can be measured to identify agents which increase functional cell surface expression of a mutant CFTR protein. In view of the amendments to claim 9, withdrawal of these rejections is respectfully requested.

IV. Rejection of Claims Under 35 U.S.C. §103

Claim 9 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Moyer et al. ((Aug. 1999) *Am. J. Physiol.* 277(2

Attorney Docket No.: **DC-0190**
Inventors: **Hamilton and Stanton**
Serial No.: **10/089,475**
Filing Date: **August 12, 2002**
Page 7

Pt 2):F271-6) in view of Cormack et al. ((1996) *Gene* 173:33-38). The Examiner suggests that Moyer et al. teach a method of measuring the effect of butyrate on expression of a CFTR-GFP nucleic acid. The Examiner further suggests that while Moyer et al. do not teach eGFP, that Cormack et al. teach mutants of GFP which fluoresce more intensely than wild-type GFP. Therefore, it is suggested that it would have been obvious to one of skill in the art at the time the invention was made to practice a method for identifying agents which increase functional cell surface expression of the deltaF508 CFTR protein by exposing cells comprising a genetic construct comprising human CFTR coding sequence and a reporter gene to the agent, measuring expression levels or trafficking of CFTR to the membrane, and comparing the levels of CFTR expression or trafficking to controls as taught in Moyer reference, wherein the reporter gene is eGFP as taught in the Cormack reference.

Applicants respectfully traverse these rejections.

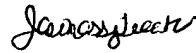
The present invention claims the benefit under 35 U.S.C. Section 119(e) of U.S. provisional applications 60/158,000 filed 6 October 1999 and 60/194,274 filed 3 April 2000. As Moyer et al. is Applicants' own publication which published within the one year grace period allowed under 35 U.S.C. §102(b), this reference has been improperly cited as basis for rejection under 35 U.S.C. §103(a). Accordingly, it is respectfully requested that this rejection be withdrawn.

Attorney Docket No.: DC-0190
Inventors: Hamilton and Stanton
Serial No.: 10/089,475
Filing Date: August 12, 2002
Page 8

V. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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